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YOUNG & THOMPSON			SUTTON, DARRYL C	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/579,919	LEFERVE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 19-46 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 19-46 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>05/19/2006</u> .	6) <input type="checkbox"/> Other: ____ .

## DETAILED ACTION

### ***Specification***

The disclosure is objected to because of the following informalities: Example 3, page 24, lists the ingredient, titanium dioxide, twice.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-28, 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will

hopefully ameliorate.’)

Mere indistinct terms (such as “stabilized starch” used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus.* See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such*

*identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful stabilized starches generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification discloses only a limited number of species at page 8, lines 21-25, and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

***Claim Rejections - 35 USC § 112, 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-28, 35, 36, 39 and 40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 39 recites the broad recitation "consisting of capsules", and the claim also recites "including hard gelatin capsules" which is the narrower statement of the range/limitation.

The term "hot conditions" in claim 40 is a relative term which renders the claim indefinite. The term "hot conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "stabilized" in claim19 is a relative term which renders the claim indefinite. The term "stabilized" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-24, 36-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lydzinski et al. (US 2003/0099692).

Lydzinski et al. teach oral films comprised of starch which are useful in delivering a variety of agents to produce pharmacological effects (Abstract and [0006]). Starch is intended to include all starches derived from natural sources [0008]. Typical sources of starches are legumes such as peas [0009]. The starch must be modified to achieve the desired film attributes [0010]. Chemically modified products include those which have been hydroxypropylated [0013]. Particularly suitable starches include hydroxypropylated starches [0017]. The starch component also comprises a cellulosic material or a gum, including hydroxyalkylcelluloses, microcrystalline cellulose, carrageenan, alginates or pullulan in amounts of less than 15% [0022]. The starch is present in amounts ranging from about 50 to about 100% [0023]. At least one plasticizer may be added to increase the apparent flexibility of the films, including polyols, such as propylene glycol, sugar alcohols such as sorbitol or polyesters such as triethyl citrate in amounts from 0 to about 15% [0026]. The film may be made by a variety of processes known in the art; films may be formed by shaping into a solidified

form by any technique known in the art, including wet casting, and extrusion molding; the solution may also be directly coated or sprayed onto another product such as a tablet and dried to form a film [0029]. A particular suitable process for preparing films is by making a solution of film components, applying the starch solution to a substrate, drying the coated substrate and removing the film from the substrate [0030]. Conventional coating processes, i.e. processes known in the art, include coating in a fluidized bed and dip-coating.<sup>1</sup>

The instant claims anticipate the instant claims insofar as it discloses a composition comprised of hydroxypropylated pea starch; further it discloses that the compositions can be used to coat solid forms by processes known in the art or to can be formed into films by applying the film to a substrate and allowing it to dry. Coating processes known in the art include spraying in a fluidized bed and dip-coating. Since the prior art teaches substantially the same starch source as the instant invention, the amylose content would be inherent to the pea starch.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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<sup>1</sup> Kim et al. US 6,123,963, column 6, lines 58-60.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(1) Claims 25-27, 29, 30, 32-35, 41, 42, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lydzinski et al. as applied to claims 19-24, 36-38 and 40 above.

Lydzinski et al. is discussed above.

Lydzinski et al. does not teach a specific embodiment comprised of a stabilized starch with an amylose content between 25% and 45% and further comprised of a plasticizer; or further comprised of a secondary film forming agent; Lydzinski et al. do not teach a pulverulent composition comprised of said starch in a secondary film forming agent in amounts of claims 29 and 30; or wherein the pulverulent composition is additionally comprised of microcrystalline cellulose; or comprised of 5 to 15% plasticizer; or wherein the secondary film forming agent is a cellulose derivative.

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such “picking and choosing” within several

variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables stabilized starch, plasticizer, secondary film forming agent, additional agents anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients hydroxypropylated pea starch; sorbitol or triethyl citrate; cellulosic materials, alginates, carrageen or pullulan; and microcrystalline

cellulose from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

In regards to claims 29, 30, 32-34 and 41-43, the prior art does not specifically teach a pulverulent composition. However, the starch and the secondary film forming agent are in a dry form, i.e. powders or granules. It would be well within the purview of the skilled artisan to combine the two components to form a pulverulent composition to which the other components are added.

In regards to claims 29, 30, 33 and 42, the prior art does not teach the specific weight percentages of the stabilized starch or of the secondary film-forming agent; or the weight percentage of the plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach the starch is present in amounts ranging from about 50 to about 100% versus 15 to 75% of instant claims 29 and 30; that the starch component also comprises a cellulosic material or a gum in amounts of less than 15% versus the 1 to 20% of instant claims 29 and 30; and that the plasticizer in amounts from 0 to about 15% versus the 5 to 15% of instant claims 33 and 42.

In regards to claims 32 and 41, the prior art does not teach a combination of a film-forming agent and microcrystalline cellulose. However, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be

useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly it would have been obvious to combine a cellulosic material, such as a hydroxyalkylcellulose and microcrystalline cellulose since both are taught to be film-forming agents individually. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness.

In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach that the starch component also comprises a cellulosic material, such as microcrystalline cellulose in amounts of less than 15% versus the 1 to 20% of instant claims 32 and 41.

In regards to claim 35, since the composition of the prior art are comprised of substantially the same components as those of the instant claim, it would reasonably be expected to exhibit substantially the same viscosity as the instant invention.

(2) Claims 19, 28, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haasmaa et al. (US 2002/0032254) in view of Leusner et al. (US 4,431,800) and further in view of Kim et al. (US 6,123,963).

Haasmaa et al. teach hydrophobic dispersions used to suitable for the production of cast films as well as coating medicinal preparations (Abstract). The purpose of coating medicinal preparations is either to cover the disagreeable taste or smell of the drug, to protect the drug against external factors during storage or dosage, to facilitate

the packaging, identification or to control the release of active substances [0019].

Polymers such as ethylcellulose are used in water-based coating preparations [0020].

The present invention is particularly suited for coating pharmaceutical preparations such as tablets, capsules and pellets [0022]. Hydrophobic starch dispersions can be produced containing a starch ether [0025]. The starch or a derivative thereof may be based on a native starch such as pea starch [0026]. The starch component is given plastic form by admixing it with a plasticizer in amounts of 0.01-95% by weight; any known plasticizer can be used, including triethyl citrate and castor oil [0031]. Typically the plasticizer is present in an amount which is 0.1 to 2 times the hydrophobic starch [0038].

Haasmaa et al. do not teach a specific embodiment comprised of a stabilized starch which has an amylose content between 25 and 45%; or the amounts of stabilized pea starch and plasticizer of claim 28; nor that the process of coating of claims 38 and 39.

Leusner et al. teach that hydroxypropylated starches are etherified starches that have reduced or decreased tendency toward retrogradation (column 1, lines 13-24), i.e. starches with improved stability.

Leusner et al. does not teach a composition comprised of stabilized pea starch.

Kim et al. teach that conventional processes for coating tablets, granules, pellets, crystals and capsules include coating in a fluidized bed and dip-coating (column 6, lines 58-65).

Kim et al. do not teach the film-forming composition of instant claim 19.

At the time of the invention, it would have been obvious to modify the pea starch of Haasmaa et al. with the methods of Leusner et al. to produce a hydroxypropylated pea starch for use as the starch component since it is a stable starch ether. It would have been obvious to use the starch composition suggested by combining Haasmaa et al. and Leusner et al. to in coating processes of Kim et al. since it teaches that conventional methods of coating capsules include fluidized bed and dip-coating.

In regard to claim 28, the prior art does not teach the specific amounts of stabilized pea starch and plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Kim et al. teaches amounts of plasticizer of 0.01 to 95% versus plasticizer in amounts of 1-2%; and that the amount of plasticizer will be from 0.1 to 2 times the amount of the starch component, i.e. the starch component can be from 0.1 to 47.5% versus stabilized pea starch in amounts of 10 to 15% of the instant claim.

(3) Claims 31 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lydzinski et al. as applied to claims 25-27, 29, 30, 32-35, 41, 42, 43 above, and further in view of Fuentes et al. (US 6,469,161).

Lydzinski et al. are discussed above.

Lydzinski et al. do not teach a hydroxypropylated and fluidification-treated pea starch.

Fuertes et al. teach a fluidification process for starchy materials (Abstract).

Fluidification techniques can be combined with other types of modification, in particular with etherification reactions. Common properties obtained include increased film strength (column 2, lines 33-45). A fluidification stage can be preceded by other chemical modifications, such as hydroxypropylation reactions (column 3, lines 1-10, column 6, lines 53-67 and column 8, lines 39-55). Starchy materials of every origin and nature can undergo the fluidification process (column 5, lines 30-34). Starchy material is understood to be all modified starches resulting from chemical modification of native starches; particularly pea starch (column 7, lines 1-10). Chemical modifications include known techniques such as etherification, particularly hydroxyalkylation (column 7, lines 24-39). The process constitutes a new, particularly straightforward, inexpensive and high performance method of obtaining converted, notably fluidified/hydroxypropylated, starchy materials. The industrial sectors concerned with starchy materials complying with the instant invention include the food and pharmaceutical industries (column 10, lines 3-16).

Fuertes et al. do not teach a composition specifically comprised of pea starch and an amount of secondary film-forming agent; or the amounts of each; or a composition comprised of pea starch and an amount of secondary film-forming agent further comprised of 1 to 20% of microcrystalline cellulose; or further comprised of a from 5-15% of plasticizer.

At the time of the invention, it would have been obvious to modify the hydroxypropylated starch of Lydzinski et al. with the methods of Fuertes et al. to

inexpensively produce a hydroxypropylated and fluidification-treated starchy material with increased film strength for use in the pharmaceutical industry, i.e., in preparing pharmaceutical compositions, as taught by Fuertes et al.

The prior art does not teach the specific weight percentages of the stabilized starch or of the secondary film-forming agent; or the amount of plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach the starch is present in amounts ranging from about 50 to about 100% versus 15 to 75% of instant claim 31; that the starch component also comprises a cellulosic material or a gum in amounts of less than 15% versus the 1 to 20% of instant claim 31; and that the plasticizer in amounts from 0 to about 15% versus the 5 to 15% of instant claim 45.

In regards to claim 44, the prior art does not teach a combination of a film-forming agent and microcrystalline cellulose. However, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly it would have been obvious to combine a cellulosic material, such as a hydroxyalkylcellulose and microcrystalline cellulose since both are taught to be film-forming agents individually. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness.

In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach that the starch component also comprises a cellulosic material, such as microcrystalline cellulose in amounts of less than 15% versus the 1 to 20% of instant claim 44.

All claims are rejected.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached

at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612